UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01-12257-PBS** **Subcategory Case No. 06-11337**
THIS DOCUMENT RELATES TO: *State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs, Inc. et al.*, Civil Action No. 03-11226-PBS	**Hon. Patti B. Saris**

DEFENDANT SANDOZ INC.'S REPLY IN SUPPORT OF ITS LOCAL RULE 56.1 STATEMENT OF UNDISPUTED FACTS AND RESPONSE TO PLAINTIFFS' STATEMENT OF ADDITIONAL UNDISPUTED FACTS IN OPPOSITION TO SANDOZ INC.'S MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56.1 of the Local Rules of this Court, Defendant Sandoz Inc. ("Sandoz") hereby respectfully submits this Reply to Plaintiffs' Response to Sandoz Inc.'s Statement of Undisputed Facts in Support of Sandoz Inc.'s Motion for Summary Judgment. Sandoz also submits the below Response to Plaintiffs' Statement of Additional Undisputed Facts in Opposition to the pending motion.

DEFENDANT SANDOZ INC.'S REPLY IN SUPPORT OF ITS LOCAL RULE 56.1 STATEMENT OF UNDISPUTED FACTS

Sandoz hereby submits its Reply in Support of its Local Rule 56.1 Statement of Undisputed Facts.

GENERAL REPLIES

1. Sandoz generally objects to Plaintiffs' responses to the extent that they raise additional factual assertions that are irrelevant and argumentative, and thus do not conform with Local Rule 56.1. *See Navarro v. U.S. Tsubaki, Inc.*, 577 F. Supp. 2d 487, 493 n.1 (D. Mass 2008) ("Rather than squarely addressing each of [Defendant's] assertions, Plaintiffs' Local Rule 56.1 filing provides a lengthy narrative of the events underlying this litigation and provides citation for every allegation to attached affidavits. Such an 'alternate statement of facts' approach does not satisfy the requirements or fulfill the purpose of Local Rule 56.1. Under such circumstances, many courts have deemed the moving party's statement admitted."); *Mercier v. Boilermakers Apprenticeship and Training Fund*, No. 07-cv-11307-DPW, 2009 WL 458556, at *9 (D. Mass. Feb. 10, 2009) (stating that the Court will "disregard arguments framed as factual assertions, and . . . consider the 'facts' asserted by each party only to the extent that they are supported by the record"). This General Reply is applicable to the following paragraphs: ¶¶ 7, 11, and 13.

2. Further, Sandoz objects to the extent Plaintiffs fail to make citations to "affidavits, depositions and other documentation" as required by Local Rule 56.1, but rather merely deny or object to the statement of undisputed fact. All such statements of undisputed fact should be deemed admitted. *See* Local Rule 56.1; *Twomey v. Nstar Elec. and Gas Corp.*, No. 09-10481-GAO, 2009 WL 5110672, at * 1 (D. Mass. Dec. 18, 2009) (noting that plaintiff's opposition motion failed to comply with Local Rule 56.1 because plaintiff failed to cite record evidence in support of motion); *Okocha v. Brigham & Women's Hosp.*, 81 F.3d 147 (1st Cir. 1996) (holding

that the lower court "properly struck plaintiff's statement of undisputed facts[] because it contained no references to any supporting documents"). This General Reply is applicable to the following paragraphs: ¶¶ 7, 12, and 13.

3. Sandoz further objects to the extent Plaintiffs fail to specifically controvert all portions of each statement of undisputed fact, and each such uncontroverted portion of a statement of undisputed fact should be deemed admitted. *See* Local Rule 56.1; *Navarro*, F. Supp. 2d at 493 n. 1 (“[U]nless the non-moving party controverts the movant's statements of undisputed fact, the movant's assertions may be deemed admitted for the purposes of the motion.”); *Clerical Apparel of New York, Inc. v. Valley Forge Insurance Co.*, 209 F.R.D. 316, 319-20 (E.D.N.Y. 2002). This General Reply is applicable to the following paragraphs: ¶¶ 8, 10, 11.

1. The Medicaid program was signed into law in 1965 as part of Title XIX of the Social Security Act and is a joint federal-state program that provides medical assistance to financially needy patients. *See* 42 U.S.C.A. § 1396-1 (2009).

   Plaintiffs' Response: Undisputed.

   Sandoz' Reply: None Required.

2. Pursuant to the Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, 104 Stat. 1388 (1990), manufacturers of prescription drugs, including Sandoz, which seek to participate in the Medicaid program under Title XIX of the Social Security Act for provision of outpatient drugs are required to enter into a rebate agreement with the Secretary of Health and Human Services. *See* 42 U.S.C.A. § 1396r-8 (2009).

   Plaintiffs' Response: Undisputed.

   Sandoz' Reply: None Required.

3. Effective January 1, 1991, Sandoz entered into such a rebate agreement with the Secretary of Health and Human Services. *See* Rebate Agreement Between The Secretary of Health and Human Services and Sandoz Inc. date stamped March 5, 1991 (hereinafter the "Rebate Agreement"), attached to the Declaration of Catherine Castaldo (hereinafter "Castaldo Decl.") as Ex. A. The Rebate Agreement remained in effect and did not substantially change from January 1, 1994 to December 31, 2004 (the "Relevant Time Period").

   Plaintiffs' Response: Undisputed that Exhibit A is a Rebate Agreement date stamped March 5, 1991. Plaintiffs dispute the balance of this Statement as Defendant has presented no evidence to support its statement that the Rebate Agreement remained in effect and did not substantially change from January 1, 1994 to December 31, 2004.

   Sandoz' Reply: Plaintiffs offer no facts to support its dispute as to the effective time period of the Rebate Agreement, which by its terms on page 1-2 provides for automatic annual renewal. The entire statement thus should be deemed admitted. *See* General Reply 2; *Okocha v. Brigham & Women's Hosp.*, 81 F.3d 147 (1st Cir. 1996).

4. The Rebate Agreement required Sandoz to, among other things, furnish certain information to the Secretary of Health and Human Services, including data regarding Average Manufacturer Price ("AMP"). *See* Castaldo Decl. Ex. A. at II(e).

   Plaintiffs' Response: Undisputed.

   Sandoz' Reply: None Required.

5. The Rebate Agreement defines AMP as "the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail class of trade." *See* Castaldo Decl. Ex. A. at I(a).

   Plaintiffs' Response: Undisputed.

   Sandoz' Reply: None Required.

6. The Rebate Agreement states that AMP "includes cash discounts allowed and all other price reductions." *See* Castaldo Decl. Ex. A at I(a).

   Plaintiffs' Response: Undisputed.

   Sandoz' Reply: None Required.

7. The State of California considered AMP to be a more accurate reflection of transaction prices for drugs than Average Wholesale Price ("AWP") and other pricing indicators.

   Castaldo Decl. Ex. B. (Transcript of Deposition of Mike Namba ("Namba Tr.") 150:5-10, Apr. 23, 2009)

   > Q: Now, have – would you agree that Average Manufacturer Price more closely approximates Average Acquisition Cost as compared to AWP?
   > A: I believe so.

   Castaldo Decl. Ex. C. (Transcript of Deposition of Vic Walker ("Walker Tr.") 161:22162:4, May 21, 2009)

   > Q: Okay. Would you consider AMP to be a better estimate of acquisition cost?
   > A: Better than what?
   > Q: AWP?
   > A: Probably.

   Castaldo Decl. Ex. D. (Transcript of Deposition of Roy Takeuchi ("Takeuchi Tr.") 146:2– 13, June 10, 2009)

   > Q: Okay. And is that consistent with your understanding that AMP was a more accurate price?
   > A: Is it a more accurate pricing? Well, I always thought that. I'm not really sure. I think that's what it was.
   > Q: In your mind AMP was a more accurate price than other prices available?
   > A: I think that's what was considered, yes.

Plaintiffs' Response: Disputed. Vague and confusing as to time. This Court has already addressed this issue at length and found AMPs to have been confidential and "not to be revealed to third parties." *Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 152 (D. Mass. 2008). Moreover, Mr. Namba and Mr. Takeuchi are long-retired, and Mr. Walker does not occupy a policy position within Medi-Cal. "The non-public or informal understandings of agency officials concerning the meaning of a regulation are [] not relevant." *United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. Mass. 2004). The testimony cited does not support the statement that "the State of California considered AMP to be a more accurate reflection of transaction prices for drugs than Average Wholesale Price ("AWP") and other pricing indicators." (*See infra*, Plaintiffs' Statement of Additional Undisputed Facts in Opposition to Sandoz, Inc.'s Motion for Summary Judgment ("CA SOAF Sandoz") ¶ 7.)

Sandoz' Reply: Sandoz' statement of fact in Paragraph 7 should be deemed admitted for the following reasons. Plaintiffs' assertion that the Court has "found AMPs to have been confidential and 'not to be revealed to third parties'" is irrelevant to Sandoz' asserted fact, and should be disregarded as an attempt to create an alternate statement of facts. *See* General Reply 1; *Navarro v. U.S. Tsubaki, Inc.*, 577 F. Supp. 2d 487, 493 n.1 (D. Mass 2008). Plaintiffs have not and cannot dispute that the three witnesses cited in Paragraph 7 testified that they believed AMP to be a more accurate reflection of transaction prices for drugs than AWP and other pricing indicators. Furthermore, Plaintiffs improperly dispute this fact without providing any citations to factual evidence in the record. *See* General Reply 2; *Okocha v. Brigham & Women's Hosp.*, 81 F.3d 147 (1st Cir. 1996).

8. Pursuant to its obligations under the Rebate Agreement, the Secretary of Health and Human Services, through CMS, is required to provide participating State Medicaid Agencies, including California, Unit Rebate Amounts (URA), which the states then use to invoice manufacturers for the rebates owed. *See* 42 U.S.C.A. § 1396r-8 (2009); Castaldo Decl. Ex. E. (Letter from Lori A. Ahlstrand, Regional Inspector for Audit Services, Dept. of Health and Human Services to Diane Bonta, Director, California Dept. of Health Services, enclosing 2003 Office of Inspector General Report: Audit of the Medicaid Drug Rebate Program in California, dated Dec. 23, 2003 CAAG/DHSE0032592 – E0032610)); *see also*

   Castaldo Decl. Ex. F. (Transcript of Deposition of Kevin Gorospe ("Gorospe Tr."), 713:16 – 714:11, Sept. 22, 2008)

> Q: Okay. And correct me if I'm wrong, but every quarter CMS or HCFA, when HCFA was the name of the agency, sends Medi-Cal a list of what's called the unit rebate amount for each drug that California reimbursed for; isn't that right?
> A: Specifically they send a file with a unit rebate amounts for all NDCs as reported to them by manufacturers, whether or not California reimbursed the product.
> Q: Oh, okay. And do you have access to that entire list?
> A: Yes.
> Q: Okay. So whether or not were reimbursed for a particular drug, you can actually look at the URA for that drug?
> A: If it was reported by the manufacturer, correct.

Castaldo Decl. Ex. G. (Transcript of Deposition of Deidre Duzor ("Duzor Tr."), 674:14-22, Mar. 26, 2008)

> Q Okay. CMS calculates the URA and it sends the URA to all the states, right?
> A: Yes.
> Q: And each state gets URAs for all the drugs that it reimburses for?
> A: Yes.
> Q: And it gets those URAs, again, by NDC number?
> A: Yes.

Plaintiffs' Response: Undisputed as to the quoted sections of the transcripts. Disputed as to the statement that "the states then use [the URAs] to invoice manufacturers for the rebates owed." (*See* Declaration of Steven U. Ross in Support of Plaintiffs' Opposition to Defendant Sandoz, Inc.'s Motion for Summary Judgment (hereinafter, "Ross Decl.") Ex. 1 (9/23/08 Douglas Hillblom Dep.) at 351:16-353:15 (manufacturers could change their URAs after receipt by California).)

Sandoz' Reply: Sandoz' statement of fact in Paragraph 8 should be deemed admitted for the following reasons. Plaintiffs' limit the dispute to the statement that "the states then use [the URAs] to invoice manufacturers for the rebates owed," but fails to actually dispute that statement, because the cited testimony of Douglas Hillblom, which concerned whether manufacturers ever updated URAs, is irrelevant to, and does nothing to refute, the stated fact, namely that the states use URAs to invoice manufacturers for the rebates owed. Plaintiffs' statement should therefore be disregarded. *See* General Reply 3; *Navarro v. U.S. Tsubaki, Inc.*, 577 F. Supp. 2d 487, 493 n.1 (D. Mass. 2008). Further, the Rebate Agreement requires

manufacturers in appropriate instances to adjust AMPs after they have been reported. *See* Rebate Agreement cited in support of Sandoz' Opening SOF ¶ 4, at 1-2.

9. From January 1, 1991 to December 31, 1993, URAs were set at 10% of AMP. From January 1, 1994 onwards, URAs were set at 11% of AMP. *See* 42 U.S.C. § 1396r-8(c)(3)(B)(2009). To calculate AMP from URA, one simply had to divide the URA amount by .1 (from 1991 to 1993) and .11 (from 1994 onwards); *see also*

   Castaldo Decl. Ex. H. (Transcript of Deposition of Larry Reed ("Reed Tr."), 1319:6 – 1321:3, Oct. 2, 2008)

   > Q: Okay, so in '91, '92, '93 they are getting URAs that at 10 percent of the AMP, correct?
   > A: Correct.
   > Q: So the state Medicaid person who got URAs during that time period could look at that URA and pretty much know exactly what the AMP is just by moving the decimal point one place, correct?
   > Q: True?
   > A: There would be a way to figure – probably a way – 10 percent would be 10 percent of AMP, so basically that's correct.
   > Q: So really it's not much of a calculation, you just have to move the decimal point, right?
   > A: It would be 10 percent.
   > Q: It would be a pretty easy calculation, correct?
   > A: Again, if it was 10 percent it would be 10 times that amount.
   > Q: Now, the next year it went to 11 percent, correct?
   > A: In the calendar year 1994.
   > Q: And it's been at 11 percent ever since, correct?
   > A: Correct.
   > Q: So again, anyone in the state Medicaid office who gets the URA for – the URAs for generic drugs can, by doing a simple mathematical computation based on 11 percent, pretty readily determine what the AMP is, correct?
   > A: Correct.

   Castaldo Decl. Ex. G. (Duzor Tr. at 679:12-21)

   > Q: Okay. So if you had the URA and you divided by .11, that would tell you what the AMP is, right?
   > A: Yes. The AMPs have been fairly transparent for generic drugs.
   > Q. If you have the URA?
   > A: Because – right, because of the simple formula.

   Plaintiffs' Response: Undisputed as to the calculation for noninnovator generic drugs. Disputed as to generic drugs on which innovator rebates were paid (including the Sandoz drugs Bromocriptine, Glyburide, Methylphenidate and Nitrofurantoin MCR).

Sandoz' Reply: The four drugs for which Plaintiffs raises a dispute are only 8 of the 149 Sandoz NDCs at issue, and concern only 3% of the claims at issue. *See* Declaration of Joshua D. Weedman (hereinafter "Weedman Decl.") Ex. D (Exhibit 7 to the Expert Disclosure of Jeffrey D. Leitzinger (Sandoz)).

10. Armed with URAs, the State of California can easily determine the AMP for a given drug.

Castaldo Decl. Ex. I. (Transcript of Deposition of Kevin Gorospe ("Gorospe Tr."), 77:9-16, Mar. 19, 2008)

> Q. So it if was ten percent -- if the rebate was ten percent of AMP and you -- all you would have to do is sort of, you know, use simple division to figure out what the AMP was based on the unit rebate amount?
> A: Correct.

Castaldo Decl. Ex. J. (Transcript of Deposition of Craig Miller ("Miller Tr."), 83:15 – 84:8 Sept. 24, 2008)

> Q: But that's something you could fairly -- at least for the noninnovator multiple source drugs we talked about a few minutes ago, that's something that if I -- if you wanted to you could figure that AMP number relatively simply; couldn't you? …
> A: Oh. Yes.
> Q: I mean you just do the math?
> A: Right.
> Q: You reverse that division –
> A: Right.
> Q: -- with a calculator, and you've got the AMP?
> A: Right.

Castaldo Decl. Ex. K. (Transcript of Deposition for Douglas Hillblom ("Hillblom Tr.") 264: 17-19, Sept. 23, 2008)

Q: How would you derive AMP from URA?
A: You'd have to take the URA amount and divide it by the appropriate percentage, and multiply it by a hundred.

Plaintiffs' Response: Disputed. Manufacturers have the ability to change the URAs provided to California. (*See* Ross Ex. 1 (9/23/08 Douglas Hillblom Dep.) at 351:16-353:15.) In addition, Plaintiff could not "easily" determine the AMP for innovator generic drugs.

Sandoz' Reply: Sandoz' statement of fact in Paragraph 10 should be deemed admitted for the following reasons. Plaintiffs' citation to testimony of Douglas Hillblom, which concerned whether manufacturers can update URAs, is irrelevant to, and does nothing to refute, the stated fact in Paragraph 10, namely that the State of California can use URAs to easily determine the AMP for a given drug. *See* General Reply 3; *Navarro v. U.S. Tsubaki, Inc.*, 577 F. Supp. 2d 487, 493 n.1 (D. Mass. 2008). The last sentence in Plaintiff's Response is irrelevant here, given its very narrow application to only 8 of the 149 NDCs at issue. *See* Sandoz' Reply in Support of its SOF, *supra*, at ¶ 9.

11. The State of California has used URA information to calculate manufacturers' AMP data.

Castaldo Decl. Ex. B. (Namba Tr. at 165:14-166:5)

> Q: And what information did you have about the – in connection with the CMS rebate? Is this – did you have AMPs, or did you have URAs? Do you recall?
> A: Yes. If the manufacturer had contacted us and was interested in pursuing additional formulary, they'd give us AMP. That was the requirement. So we had it. But we could also calculate from the CMS information that we had, because our rebate was set at 11 percent fixed.

Castaldo Decl. Ex. B. (Namba Tr. at 166:16 – 167:3)

> Q: Okay. But … you just noted that you could find – from the unit rebate amount you could – you could calculate the – what the AMP would be?
> A: For generic drugs.
> Q. For generic drugs right. And so you saw, when you calculated AMP for the generic drug, that it – it was a very low number; right?
> A: Correct.

Plaintiffs' Response: Disputed. The testimony cited by Defendant does not support the statement that California used URA information to calculate manufacturers' AMP data. (*See* CA SOAF Sandoz, ¶ 4 (California did not calculate AMPs from URAs); Ross Ex. 2 (10/22/08 Craig Miller Dep.) at 234:6-22.)

Sandoz' Reply: Sandoz' statement of fact in Paragraph 11 should be deemed admitted for the following reasons. Plaintiffs cite to transcript testimony that is irrelevant to, and does nothing to refute, the stated fact in Paragraph 11, namely that the State of California has used

URAs to easily determine the AMP for a given drug. *See* General Reply 3; *Navarro v. U.S. Tsubaki, Inc.*, 577 F. Supp. 2d 487, 493 n.1 (D. Mass. 2008). Indeed, Plaintiffs' cited testimony from Mr. Craig Miller is not based on personal knowledge, is not admissible, and does not mention calculating AMPs from URAs at all, but instead simply states that Mr. Miller heard that California did not compare AMPs and URAs to AWPs. That is not the substance of Sandoz' Statement of Fact in Paragraph 11. Furthermore, as the evidence cited by Sandoz in support of Paragraph 11 demonstrated, Mike Namba, a Medi-Cal employee, testified that, from a URA, he could and did calculate AMPs for generic drugs. Plaintiffs' purported evidence does not address the substance of Mr. Namba's statement and the resultant fact in Paragraph 11. Consequently, Paragraph 11 should be deemed admitted. *See* General Reply 1; *Navarro*, 577 F. Supp. 2d at 493 n.1.

12. Notwithstanding its obligations to provide AMP data to the federal government pursuant to the Rebate Agreement, beginning on July 16, 1991, Sandoz voluntarily provided the State of California with its AMP data. See Castaldo Decl. Ex. L. (Letter from Beth Brannan, Manager, Government Affairs, Geneva Pharmaceuticals, Inc. (Sandoz) to Michael Neff, California Dept. of Health Services enclosing AMP data, dated July 16, 1991 (SANDOZ CALI 3000033)); see also

    Castaldo Decl. Ex. D. (Takeuchi Tr. at 145:3 -22)

    > Q: Mr. Takeuchi, -- based on Exhibit 17 through 19 would you agree with me that California received Sandoz' AMPs for its products reimbursed by California.
    > A: Just what I see, it looks like it.
    > Q: Okay.
    > A: I don't know if that's everything.
    > Q: But California did receive AMPs for at least some products from Geneva from 1992 through 1996; correct?
    > A: If – if the mailing and everything else was correct, looks like it.

    Plaintiffs' Response: Undisputed that Defendant provided AMP data to California on or about July 16, 1991. Vague and confusing thereafter as to time. Disputed that Defendant *voluntarily* provided such data. (*See* CA SOAF Sandoz ¶ 1 (From 1991 through 1996 California required each drug manufacturer whose products were on the Medi-Cal formulary, including Defendant Sandoz, Inc., to provide California with AMP data in connection with supplemental rebate contracts entered into between California and each

drug manufacturer, including Defendant Sandoz, Inc.); Ross Ex. 3 (4/23/09 Mike Namba Dep.) at 155:4-8.)

Sandoz' Reply: Sandoz' statement of fact in Paragraph 12 should be deemed admitted for the following reasons. Plaintiffs improperly dispute this fact without providing any citations to factual evidence demonstrating that Sandoz did not voluntarily provide California with AMPs beginning on or about July 16, 1991. *See* General Reply 2; *Okocha v. Brigham & Women's Hosp.*, 81 F.3d 147 (1st Cir. 1996). Notably, California cites to no rebate agreements or other documentary evidence to support its assertion that Sandoz was required to produce AMP data to California as part of a mandatory supplemental rebate program. This is because California witnesses have explained that the program was *not* mandatory and companies could choose to not participate. *See, e.g.*, Weedman Decl. Ex. E (12/3/08 Rule 30(b)(6) Cal. Dept. Health Care Services (Gorospe) Dep. at 73:22-74:5); Weedman Decl. Ex. F (4/28/09 Miller Dep. at 364:4-366:4). Plaintiffs' claim that the time period is "vague and confusing" ignores the cited evidence, which shows that Sandoz provided AMPs for each NDC from 1991 to 1997, and its own opposition brief, which concedes the point at page 3. *See* Weedman Decl. Ex. G (Table of Sandoz AMP Letters to California).

13. Sandoz continued to directly provide the State of California with its AMP data until March 21, 1997. See Castaldo Decl. Ex. M. (Letter from Ron Hartmann, Manager, Government Affairs, Geneva Pharmaceuticals, Inc. (Sandoz) to State of California enclosing AMP data, dated Mar. 21, 2007 (SANDOZ CALI 3001109)).

Plaintiffs' Response: Disputed. Although Sandoz may have transmitted AMP data in 1997, the AMP data referred to periods in 1996, pursuant to the supplemental rebate agreement between Plaintiff and Sandoz. (See CA SOAF Sandoz ¶ 1 (From 1991 through 1996 California required each drug manufacturer whose products were on the Medi-Cal formulary, including Defendant Sandoz, Inc., to provide California with AMP data in connection with supplemental rebate contracts entered into between California and each drug manufacturer, including Defendant Sandoz, Inc.); Ross Ex. 3 (4/23/09 Mike Namba Dep.) at 155:4-8.)

Sandoz' Reply: Sandoz' statement of fact in Paragraph 13 should be deemed admitted for the following reasons. Plaintiffs do not dispute that Sandoz directly provided the State of California with its AMP data until March 21, 1997. As such, this statement is undisputed and deemed admitted. *See also* Sandoz' Reply in Support of SOF, *supra*, at ¶ 12.

Plaintiffs, however, improperly "dispute" this fact by contending that Sandoz provided AMP data that "referred to periods in 1996, pursuant to the supplemental rebate agreement between Plaintiff and Sandoz." This statement does not squarely address the statement of fact in Paragraph 13 and should consequently be rejected. *See* General Reply 1; *Navarro v. U.S. Tsubaki, Inc.*, 577 F. Supp. 2d 487, 493 n.1 (D. Mass. 2008). Furthermore, Plaintiffs' citation does not support the proposition that Sandoz and California entered into any supplemental rebate program, and Plaintiffs have offered no other evidence to support its contention. *See* General Reply 2; *Okocha v. Brigham & Women's Hosp.*, 81 F.3d 147 (1st Cir. 1996). Notably, California cites to no rebate agreements or other documentary evidence to support its assertion that Sandoz was required to, or in fact did, produce AMP data to California as part of a mandatory supplemental rebate program. Medi-Cal officials explained that the program was not mandatory and companies could choose to not participate. *See, e.g.*, Weedman Decl. Ex. E (12/3/08 Rule 30(b)(6) Cal. Dept. Health Care Services (Gorospe) Dep. at 73:22-74:5); Weedman Decl. Ex. F (4/28/09 Miller Dep. at 364:4-366:4). Indeed, Medi-Cal personnel have testified that supplemental rebate programs in California were not successful with generic manufacturers because those manufacturers had no desire to participate. *See* Weedman Decl. Ex. H (3/19/08 Gorospe Dep. at 71:11-17); Weedman Decl. Ex. I (5/6/09 Rule 30(b)(6) Cal. Dept. Health Care Services (Gorospe) Dep. at 341:19-342:5).

Furthermore, it is unclear from the record how long the mandatory supplemental rebate program lasted. For example, one Medi-Cal official testified that the program began in 1992. *See* Weedman Decl. Ex. F (4/28/09 Miller Dep. at 363:18-21). Another Medi-Cal official testified that the program lasted only from 1994 to 1996. *See* Weedman Decl. Ex. J (9/22/08 Gorospe Dep. at 704:19 – 705:17). Notwithstanding, Sandoz' reporting of AMPs extended both before the supplemental rebate program began and after it ended. *See* Weedman Decl. Ex. G (Table of Sandoz AMP Letters to California).

SANDOZ INC.'S RESPONSES TO PLAINTIFFS' SEPARATE STATEMENT OF ADDITIONAL UNDISPUTED FACTS IN OPPOSITION TO SANDOZ INC.'S MOTION FOR SUMMARY JUDGMENT

If a statement of additional fact asserted by Plaintiffs is undisputed, it is undisputed solely for the purposes of this motion, and Sandoz reserves the right to dispute any statement in future proceedings. To the extent that any of Plaintiffs' statements of additional fact are immaterial, not properly supported by the record, argumentative, or conclusory assertions, such statements should be rejected under Local Rule 56.1. *See, e.g.*, *O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006) (disregarding "purported statements of 'fact' not properly supported by citations to the record" in summary judgment pleadings as required by Local Rule 56.1); *Mercier v. Boilermakers Apprenticeship and Training Fund*, No. 07-cv-11307-DPW, 2009 WL 458556, at *9 (D. Mass. Feb. 10, 2009) (stating that the Court will "disregard arguments framed as factual assertions, and . . . consider the 'facts' asserted by each party only to the extent that they are supported by the record").

1. From 1991 through 1996 California required each drug manufacturer whose products were on the Medi-Cal formulary, including Defendant Sandoz, Inc., to provide California with AMP data in connection with supplemental rebate contracts entered into between California and each drug manufacturer, including Defendant Sandoz, Inc. (Ross Ex. 3 (4/23/09 Mike Namba Dep.) at 155:4-8.)

SANDOZ RESPONSE TO PARAGRAPH 1

It is irrelevant whether Sandoz provided its AMPs voluntarily or under a rebate agreement with California, the relevant undisputed fact is that California received Sandoz' AMPs for that time period. Furthermore, Plaintiffs' citation does not support the proposition that Sandoz and California entered into any supplemental rebate program, and Plaintiffs have offered no other evidence to support its contention. Notably, California cites to no rebate agreements or other documentary evidence to support its assertion that Sandoz was required to, or in fact did,

produce AMP data to California as part of a mandatory supplemental rebate program. Medi-Cal officials explained that the program was *not* mandatory and companies could choose to not participate. *See, e.g.*, Weedman Decl. Ex. E (12/3/08 Rule 30(b)(6) Cal. Dept. Health Care Services (Gorospe) Dep. at 73:22-74:5); Weedman Decl. Ex. F (4/28/09 Miller Dep. at 364:4-366:4). Indeed, Medi-Cal personnel have testified that supplemental rebate programs in California were not successful with generic manufacturers because those manufacturers had no desire to participate. *See* Weedman Decl. Ex. H (3/19/08 Gorospe Dep. at 71:11-17); Weedman Decl. Ex. I (5/6/09 Rule 30(b)(6) Cal. Dept. Health Care Services (Gorospe) Dep. at 341:19-342:5). Sandoz further asserts that the fact statement is not supported by the cited evidence which takes the deposition testimony of Mike Namba out of context. Mr. Namba was testifying as to a *voluntary* supplemental rebate program that was in operation during the time he worked as a Medi-Cal pharmaceutical consultant from 2000 to 2006. Nowhere in the cited testimony does Mr. Namba testify about manufacturers being required to submit AMPs as part of a supplemental rebate program from 1991 to 1996. *See* Weedman Decl. Ex. K (4/23/09 Namba Tr. at 150:12 – 155:8.)

2. The AMP data that California received from the drug manufacturers was given to the EDS drug rebate unit to validate that the format was followed and that there were no errors, and was then turned over to the EDS system's group who would load the data into the system to calculate the supplemental rebates. (Ross Ex. 4 (10/21/08 Maureen Tooker Dep.) at 17:21- 18:22.)

   SANDOZ' RESPONSE TO PARAGRAPH 2

   Undisputed; however this fact is irrelevant.

3. California used the AMP data received from drug manufacturers for the calculation of supplemental rebates only. (Ross Ex. 2 (10/22/08 Craig Miller Dep.) at 320:10- 321:4.)

SANDOZ' RESPONSE TO PARAGRAPH 3

Sandoz does not dispute that California used AMP data it received from manufacturers pursuant to valid rebate contracts to calculate supplemental rebates under such contracts. The cited evidence, however, does not support any inference that California "only" used AMP data for the calculation of supplemental rebates. Mr. Miller's testimony merely states that AMP data was used in the calculation of supplemental rebates. The statement is, nonetheless, irrelevant.

4. California did not calculate AMPs from URAs. (Ross Ex. 2 (10/22/08 Craig Miller Dep.) at 234:6-22.) Manufacturers could and did change or restate the AMPs which they previously provided to California, causing AMP data to be unreliable. (Ross Ex. 12 (3/19/08 Kevin Gorospe Dep.) at 373:6-18, 374:8-375:10.)

SANDOZ' RESPONSE TO PARAGRAPH 4

Sandoz does not dispute that the terms of the Rebate Agreement required manufacturers to adjust AMPs in certain instances. *See* Rebate Agreement as cited in Sandoz SOF ¶ 4, at 1-2. Sandoz disputes the first statement as unsupported by the cited testimony and contrary to undisputed facts. *See* Sandoz' Reply in Support of SOF, *supra*, at ¶ 11. Sandoz disputes the statement that adjusting AMPs causes them to be unreliable as unsupported by the cited testimony of Dr. Gorospe, which only states that AMP can be adjusted and offers no facts suggesting any Sandoz AMP was unreliable, and which is inadmissible pursuant to Rule of Evidence 611(c). *See also* Sandoz' Response to Plaintiffs' Additional SOF, *infra*, at ¶¶ 10-17.

5. Unless California law allowed for the use of AMPs as a basis for reimbursement, California did not use AMPs in connection with discussions about reimbursement or policy decisions concerning reimbursement. (Ross Ex. 5 (9/22/08 J. Kevin Gorospe Dep.) at 671:11-19; Ross Ex. 1 (9/23/08 Douglas B. Hillblom Dep.) at 265:10-266:6.)

SANDOZ' RESPONSE TO PARAGRAPH 5

Irrelevant. *See* Sandoz' Opening SOF ¶ 7. Disputed as unsupported by the cited material is any inference that California could not have compared AMP to AWP or other information, such as reimbursement payments. *See id.*

6. California did not use URAs in connection with discussions about reimbursement or policy decisions concerning reimbursement. (Ross Ex. 1 (9/23/08 Douglas B. Hillblom Dep.) at 265:10-266:6.)

SANDOZ' RESPONSE TO PARAGRAPH 6

Irrelevant. *See* Sandoz' Opening SOF ¶ 7. Disputed as unsupported by the cited material is any inference that California could not have compared AMP to AWP or other information, such as reimbursement payments. *See id.*

7. California did not compare AMPs or URAs with any other pricing information, including AWPs. (Ross Ex. 2 (10/22/08 Craig Miller Dep.) at 316:18-319:16.)

SANDOZ' RESPONSE TO PARAGRAPH 7

The cited testimony does not support the asserted fact. Mr. Miller testified that he did, in fact, see AMP and AWP price comparisons, and that such comparisons were done by others. *See* Weedman Decl. Ex. L (10/22/08 Miller Dep. at 316:18-319:16); *see also* Weedman Decl. Ex. M (9/24/08 Miller Dep. at 127:9 – 130:6); Weedman Decl. Ex. N (9/24/08 Miller Dep. Ex. 2). Further, Mr. Mike Namba, Chief of the Pharmacy Contract Unit, testified that California calculated the AMP from URAs for generic drugs. *See* Sandoz' Opening SOF ¶ 11.

8. California has always treated AMP data as confidential under federal law. (Ross Ex. 6 (12/3/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Gorospe) Dep.) at 283:14-284:3.)

SANDOZ' RESPONSE TO PARAGRAPH 8

Undisputed as to the confidentiality provision of federal law. Disputed as to any inference that confidentiality prevented California from comparing AMPs to AWPs, or other

information. *See* Joint Response to Plaintiffs' Additional SOF ¶ 26 (discussing scope of federal law).

9. California believed that using AMP data to establish a reimbursement formula would breach the confidentiality afforded to AMPs under federal law. (Ross Ex. 6 (12/3/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Gorospe) Dep.) at 284:15-285:8.)

SANDOZ' RESPONSE TO PARAGRAPH 9

Sandoz does not dispute that Dr. Kevin Gorospe, Chief of the Medi-Cal Pharmacy Policy unit, testified that establishing a formula based directly on AMP could be a breach of confidentiality. Sandoz disputes any inference that California was prohibited from comparing AMP to AWPs or reimbursement amounts, or other price information. *See* Joint Response to Plaintiffs' Additional SOF ¶ 26 (discussing scope of federal law).

10. In May 2007, a representative of Defendant Mylan met with Dr. Kevin Gorospe, Chief of the Medi-Cal Pharmacy Policy Unit at the California Department of Health Care Services. The meeting included a discussion about AMPs in which the Mylan representative described AMPs as a poor basis for reimbursement because they were unreliable. (Ross Ex. 5 (9/22/08 J. Kevin Gorospe Dep.), at 693:7-694:5.)

SANDOZ' RESPONSE TO PARAGRAPH 10

Undisputed that Dr. Gorospe testified he met with a Mylan representative in May 2007. Testimony as to Mylan's views on AMPs, however, is inadmissible hearsay as to Sandoz. The asserted facts in the last sentence, moreover, are irrelevant because they concern AMPs after the relevant time period in this case. *See* Sandoz' Response to Plaintiffs' Additional SOF at ¶ 11 (discussing changes in the law in 2005). And they are unsupported by the cited testimony, which consists of Plaintiffs' counsel's misstatement of prior testimony in a leading question. Mr. Gorospe's testimony regarding the meeting with the Mylan representative was that he did not recall the content of the discussion on reliability. *See* Weedman Decl. Ex. J (9/22/08 Gorospe Dep. at 694: 6-13).

11. At the meeting in May 2007, the Mylan representative presented Dr. Gorospe with a report prepared by GPhA which stated that AMPs were inappropriate for use as the basis for pharmacy reimbursement for a variety of reasons. (Ross Ex. 5 (9/22/08 J. Kevin Gorospe Dep.) at 654:14-657:7.)

SANDOZ' RESPONSE TO PARAGRAPH 11

Sandoz does not dispute that Dr. Gorospe was presented with a GPhA report in May of 2007. However, Sandoz disputes that the truth or falsity of this statement is relevant to this Court's determination of summary judgment. The report is irrelevant because it was drafted and circulated after the relevant time period in this case, and any policy judgments regarding use of AMPs for reimbursement in 2007 are irrelevant to the knowledge available to California from AMPs during the relevant time period. Furthermore, the report concerns statutory and regulatory changes following the Deficit Reduction Act of 2005 that post-date the relevant time period in this case. *See* Sandoz' Reply in Support of Motion for Summary Judgment at 7-8. The report discusses AMPs and other issues in a context completely different from that at issue in this case. The Deficit Reduction Act changed how AMPs were to be calculated, changed how often they were to be reported and changed the level of confidentiality applicable to AMP information. *See* Medicaid Program Prescription Drugs, 71 Fed. Reg. 77175 (proposed Dec. 22, 2006) (to be codified at 42 C.F.R. pt. 447) (outlining changes made by the Deficit Reduction Act of 2005). Sandoz refers to the cited document for its content, which Plaintiffs' proposed statement does not accurately describe, and Sandoz' response to Paragraph 13, *infra*, which addresses Plaintiffs' misreading of similar materials.

12. In October 2005 GPhA sent a letter to Charles Grassley, Chairman, Committee on Finance, and to Max Baucus, Ranking Member, Committee on Finance for the purpose of cautioning the United States Senate Committee on Finance about using AMPs as a basis to calculate pharmacy reimbursement, as AMPs did not represent an accurate reflection of true market prices. (Ross Ex. 7 (2/10/09 Rule 30(b)(6) Generic Pharmaceutical Association (Brown) Dep.) at 75:18-77:17, referring to Ex. 57.)

SANDOZ' RESPONSE TO PARAGRAPH 12

Sandoz does not dispute that the GPhA sent a letter to Messrs. Grassley and Baucus in October 2005, and refers the Court to that one page letter for its contents, which are not accurately described in the asserted fact statement. The letter suggests that an undescribed AMP-based model would reimburse pharmacies below cost, which would jeopardize access, and supports a reimbursement model which is "market-based, accurately reflects pharmacy acquisition costs, encouraged generic utilization, and ensures fair and adequate reimbursement to pharmacists." The document is irrelevant, however, because it post-dates the relevant time period and concerns undefined proposed (not actual) legislative changes to the AMPs as they existed in the relevant time period. *See* also Sandoz' Responses to ¶¶ 11, 13.

13. In February 2007 GPhA sent a letter to the Centers for Medicare & Medicaid Services ("CMS") advising CMS that AMPs are easily misinterpreted "when payers, state agencies and consumers rely on AMPs to indicate actual prices available in the marketplace." (Ross Ex. 7 (2/10/09 Rule 30(b)(6) Generic Pharmaceutical Association (Brown) Dep.) at 78:15- 80:8, referring to Ex. 58.)

SANDOZ' RESPONSE TO PARAGRAPH 13

Sandoz does not dispute that the GPhA sent a letter to CMS in February of 2007, and refers the Court to that letter for its content, which is not accurately portrayed in the asserted fact statement. The letter is irrelevant, however, because it concerns statutory and regulatory changes following the Deficit Reduction Act of 2005 that post-date the relevant time period in this case. *See* Sandoz' Reply in Support of Motion for Summary Judgment at 7-8. Among other things, the Deficit Reduction Act changed how AMPs were to be calculated, changed how often they were to be reported and changed the level of confidentiality applicable to AMP information. *See* Medicaid Program Prescription Drugs, 71 Fed. Reg. 77175 (proposed Dec. 22, 2006) (to be codified at 42 C.F.R. pt. 447) (outlining changes made by the Deficit Reduction Act of 2005).

Moreover, the letter is quoted out of context to mislead as to its meaning. The 18 page letter provides a detailed analysis of CMS' proposed regulations, designed to implement the changes mandated by the DRA. The initial overview at page 2 explains that AMPs can be "misinterpreted when payers, state agencies and consumers rely on AMPs to indicate actual prices available in the marketplace." *See* Weedman Decl. Ex. O (GPhA Letter to Centers for Medicare & Medicaid Services ("CMS") (hereinafter "GPhA Letter"), Feb. 20, 2007). The letter immediately explains the reasons, namely, like any similar average, AMPs "represent a snapshot in time…of a complex set of sales records." The letter expands upon this at page 3 under the section "Limitations on the Usefulness of AMP," which explains that (i) "normal business activities cause periodic deflations or inflations of AMP from month to month," including backorders, temporary discontinuations and low demand; and that (ii) timing differentials between the initial sale and application of later credits, such as market share rebates, or stocking adjustments, which are of necessity processed on a lag, affect AMPs like they would similar averages. *See* GPhA Letter at 3.

The letter explains in further detail, by way of an example using stocking adjustments issued subsequent to the initial sale, the conceptual issues created by using a month's average, before all information regarding the transaction has been received:

> For example, if the manufacturer had a price of $20 during January 2006 and lowered the price to $12 during February 2006, then an adjustment claim of $8 a bottle would be processed in March 2006 when the price is $12 and give the false impression via AMP of a net $4 price or less during March 2006 ($12 new price less the $8 adjustment for January 2006 delivery) depending on the customer inventory levels of adjustment.

See GPhA Letter at 3.

The letter explains even further under the heading "Confusion Among Purchasers and Payors" the concerns GPhA had regarding use of AMP as an indicator of "market" prices

without further clarification and understanding of the calculation. *See* GPhA Letter at 6. Specifically, the letter explains that a manufacturer with sales to a single entity, or one with sales to a few large volume purchasers at discounted prices, could have comparatively low prices that may not be available to all purchasers. Thus,

> [b]ecause purchasers and payers viewing these published prices would not know the reasons for the low AMPs, they might mistakenly think the prices are widely available and that the prices they have paid are unreasonable in comparison. Moreover, all the published prices – even those that are not unusually low or temporarily deflated – would represent wholesale prices and not prices to the ultimate consumers, which would include dispensing fees and wholesale/distributor markup fees. Thus, even published prices that were widely available as wholesaler prices would seem low to certain purchasers, who would likely be unaware of the nature of the published prices. Month-to-month fluctuations in manufacturers' AMPs (for reasons discussed above) would also be likely to confuse customers who were unfamiliar with the many complicated transactions in pharmaceutical manufacturing and sales.

Id.

The GPhA goes on to suggest various ways to ameliorate these and other issues:

> We support smoothing with an annual period rather than with a three-month period because the longer time period allows the AMPs to be less volatile. Smoothing has produced positive results in ASP pricing for Medicare Part B drugs, particularly in Healthcare Common Procedure Coding System ("HCPCS") codes that apply to multiple source products. Generic products are particularly well-suited for smoothing, due to the need to account for, in AMP, discontinued products, backordered products, and the large dollar value of chargebacks customarily processed for wholesaler sales for generic products.

GPhA Letter at 14.

14. In 2005 GPhA created the Medicaid Task Force (also called the AMP Task Force) in response to the proposed federal Deficit Reduction Act. The purpose of the Medicaid Task Force was to address the concerns of the generic pharmaceutical industry about AMPs. As of 2007 Defendant Sandoz was a member of the Medicaid Task Force. (Ross Ex. 7 (2/10/09 Rule 30(b)(6) Generic Pharmaceutical Association (Brown) Dep.) at 55:9-56:11.)

SANDOZ' RESPONSE TO PARAGRAPH 14

Undisputed that the GPhA created a Medicaid Task Force and that Sandoz was a member in 2007. However, Sandoz disputes that the truth or falsity of this statement is relevant to this Court's determination of summary judgment. The creation of the Medicaid Task Force post-dates the relevant time period in this case. Furthermore, any concerns the GPhA had about AMPs in 2007 are irrelevant to the issues in this case because they are responsive to a reimbursement regime that was fundamentally altered by the Deficit Reduction Act of 2005. Among other things, the Deficit Reduction Act changed how AMPs were to be calculated, changed how often they were to be reported and changed the level of confidentiality applicable to AMP information. *See* Medicaid Program Prescription Drugs, 71 Fed. Reg. 77175 (proposed Dec. 22, 2006) (to be codified at 42 C.F.R. pt. 447) (outlining changes made by the Deficit Reduction Act of 2005). Because the Deficit Reduction Act was passed after the relevant time period in this case, the changes it implemented and issues it created are irrelevant. *See* Sandoz' Response to Plaintiffs' Additional SOF at ¶ 13.

15. In 2007 attorneys for GPhA prepared a "white paper" for California, the purpose of which was to explain the position of GPhA that AMPs were not an adequate basis upon which to calculate pharmacy reimbursement, to talk about the limitations of AMPs and to express concerns about the confidentiality of AMPs. (Ross Ex. 7 (2/10/09 Rule 30(b)(6) Generic Pharmaceutical Association (Brown) Dep.) at 39:12-41:18, referring to Ex. 53.)

SANDOZ' RESPONSE TO PARAGRAPH 15

Sandoz does not dispute that the GPhA created a "white paper" in 2007, and refers the Court to that document for its content, which Plaintiffs' proposed statement does not describe accurately, and is thus disputed as unsupported by the cited material. Sandoz incorporates by reference its Response to Paragraph 13, which discusses at length what is essentially the same

document, and explains the GPhA's positions, provides proper context for them, and explains why they are not relevant.

16. Prior to the GPhA white paper being sent to California, it was reviewed by members of the GPhA State Government Affairs Committee. Defendant Sandoz, Inc. was a member of that committee. (Ross Ex. 7 (2/10/09 Rule 30(b)(6) Generic Pharmaceutical Association (Brown) Dep.) at 42:1-19, referring to Ex. 53.)

SANDOZ' RESPONSE TO PARAGRAPH 16

Irrelevant. Sandoz incorporates by reference its Response to Paragraph 15, and disputes as unsupported (though irrelevant) any inference Sandoz reviewed the "white paper."

17. In its white paper sent to California, GPhA talked about the fluctuations of AMPs and why AMPs would be unreliable data points to try to calculate pharmacy reimbursement. The white paper further set out the positions of GPhA that AMPs are mistakenly perceived as indicators of market prices, and that AMPs bear little relevance to market prices. None of GPhA's members, including Defendant Sandoz, Inc., disagreed with these positions. (Ross Ex. 7 (2/10/09 Rule 30(b)(6) Generic Pharmaceutical Association (Brown) Dep.) at 45:6-51:14, referring to Ex. 53.)

SANDOZ' RESPONSE TO PARAGRAPH 17

Sandoz does not dispute that the GPhA created a "white paper" in 2007, and refers the Court to that document for its content, which Plaintiffs' proposed statement does not describe accurately, and is thus disputed as unsupported by the cited material. Sandoz incorporates by reference its Response to Paragraph 13, which discusses at length what is essentially the same document, and explains the GPhA's positions, provides proper context for them, and explains why they are not relevant.

18. According to GPhA, using AMPs would not be an accurate way of calculating the price charged by a manufacturer to consumers. (Ross Ex. 7 (2/10/09 Rule 30(b)(6) Generic Pharmaceutical Association (Brown) Dep.) at 51:20-52:19, 98:8-14.)

SANDOZ' RESPONSE TO PARAGRAPH 18

Sandoz disputes Paragraph 18 as misleading, incomplete and unsupported by the record citation, and refers to its Response to Paragraph 13 for a description of the GPhA's position, in

proper context, and explanation as to why such evidence is irrelevant here. Sandoz does not sell its products directly to consumers, and the purported fact statement is irrelevant to the undisputed fact that California could measure the difference between AMPs and AWPs to understand net prices received by Sandoz for drugs distributed through the retail class of trade. *See* Sandoz' Opening SOF at ¶ 7.

19. A representative from Sandoz, Inc. (traditionally the CEO) has always sat on the Board of Directors of GPhA, and the GPhA Executive Committee. (Ross Ex. 8 (5/6/09 Rule 30(b)(6) Sandoz, Inc. (Hartmann) Dep.) at 370:19-371:17.)

SANDOZ' RESPONSE TO PARAGRAPH 19

Undisputed for purposes of this motion but irrelevant. Sandoz disputes any inference that by holding these positions in the GPhA organization Sandoz adopts any GPhA statements.

20. Sandoz, Inc. was a member of GPhA's Medicaid Task Force. (Ross Ex. 8 (5/6/09 Rule 30(b)(6) Sandoz, Inc. (Hartmann) Dep.) at 372:7-13.)

SANDOZ' RESPONSE TO PARAGRAPH 20

Undisputed for purposes of this motion but irrelevant. Sandoz disputes any inference that by holding this position in the GPhA organization Sandoz adopts any GPhA statements.

21. Sandoz, Inc. agreed with the position taken by GPhA that "AMP is mistakenly perceived as an indicator of market prices, however, it bears little relevance to market price." (Ross Ex. 8 (5/6/09 Rule 30(b)(6) Sandoz, Inc. (Hartmann) Dep.) at 398:13-399:11.)

SANDOZ' RESPONSE TO PARAGRAPH 21

Sandoz disputes Paragraph 21 as misleading, incomplete and unsupported by the record citation, and refers to its Response to Paragraph 13 for a description of the GPhA's position, in proper context, and explanation as to why such evidence is irrelevant here.

22. Sandoz, Inc. never explained to anyone at California's Department of Health Services the difference between provider actual acquisition costs for its drugs and its reported AWPs. (Ross Ex. 9 (11/6/08 CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 302:8-15; Ross Ex. 5 (9/22/08 Kevin Gorospe Dep.), at 698:14-19.)

SANDOZ' RESPONSE TO PARAGRAPH 22

Sandoz objects to the testimony cited in Paragraph 22 as violative of Rule 611(c) of the Federal Rules of Evidence, on the grounds that it was elicited from a witness produced by California through leading questions asked by California's counsel during direct examination. Sandoz provided its AMP information directly to California from 1991 to 1997. *See* Sandoz' Opening SOF ¶¶ 12-13. AMP data represents a federally-mandated average, based on transactional information, of the net prices received by Sandoz for drugs sold directly or indirectly (ie., via wholesalers) to the retail class of trade. California also had substantial information regarding generic drug pricing and its relationship to AWP. *See* Joint SOF ¶¶ 24, 26, 27, 32, 38, 48, 52, 55, 58. Sandoz disputes as unsupported by the cited testimony any inference that it was required to report some undefined net average of transaction prices to California.

23. It has never been the policy of California's Medi-Cal program to deliberately accept inflated and inaccurate AWPs because the program knew this would offset low dispensing fees to pharmacists. (Ross Ex. 9 (11/6/08 CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 313:10-19.)

SANDOZ' RESPONSE TO PARAGRAPH 23

Sandoz objects to the testimony cited in Paragraph 23 as violative of Rule 611(c) of the Federal Rules of Evidence, on the grounds that it was elicited from a witness produced by California through leading questions asked by California's counsel during direct examination. Further, Paragraph 23 is argument and does not satisfy the requirements of Rule 56.1 *See Mercier v. Boilermakers Apprenticeship and Training Fund*, No. 07-cv-11307-DPW, 2009 WL 458556, at *9 (D. Mass. Feb. 10, 2009) (stating that the Court would "disregard arguments framed as factual assertions" in the parties' 56.1 statements). To the extent a response is required, Sandoz notes that California deliberately adopted a reimbursement methodology that it

knew would pay providers more than their actual acquisition costs for drugs to achieve its own policy goals, including compensating providers for inadequate dispensing fees. *See* Joint SOF ¶¶ 24-26, 33, 35-40, 52-53, 55, 67.

24. Sandoz, Inc. did not report its transactional prices, nor any average or compilation of these prices, to the pricing compendia or to Medi-Cal as its products' AWPs or otherwise. (Ross Ex. 10 (1/27/09 Frank Stiefel Dep.) at 379:19-380:7.)

SANDOZ' RESPONSE TO PARAGRAPH 24

Unsupported by cited testimony. Mr. Stiefel was only employed at Sandoz for three years and his job responsibilities did not include reporting prices to pricing compendia or communicating with Medi-Cal. *See* Weedman Decl. Ex. P (11/13/08 Steifel Dep. at 39:13-40:4, 68:18-23). Sandoz provided its AMP information directly to California from 1991 to 1997. *See* Sandoz SOF ¶¶ 12-13. AMP data represents a federally-mandated average, based on transactional information, of the net prices received by Sandoz for drugs sold directly or indirectly (ie., via wholesalers) to the retail class of trade. California also had substantial information regarding generic drug pricing and its relationship to AWP. *See* Joint SOF ¶¶ 24, 26, 27, 32, 38, 48, 52, 55, 58.

25. There was no fixed or predictable relationship between the AWPs that Sandoz, Inc. reported to FDB and the prices at which its products were sold to the retail class of trade. (Ross Ex. 11 (6/11/07 Kevin Galownia Dep.) at 169:5-17.)

SANDOZ' RESPONSE TO PARAGRAPH 25

Misleading and incomplete. To avoid repetition, Sandoz incorporates by reference Paragraphs 7-9 of its Response to Plaintiffs' Local Rule 56.1 Statement of Undisputed Facts as to Defendant Sandoz Inc., which address the same assertion, and explain Sandoz' pricing in proper context. Sandoz also notes that it did not know the final selling price between wholesalers and retailers for Sandoz' drugs. *See* Weedman Decl. Ex. Q (3/26/08 Worrell Dep. at 401:7-17).

26. Sandoz, Inc. was aware of or on notice that Medi-Cal reimbursed providers for pharmaceutical products based on the reported AWPs of its products. (Ross Ex. 8 (5/6/09 Rule 30(b)(6) Sandoz, Inc. (Hartmann) Dep.) at 330:21-332:14.)

SANDOZ' RESPONSE TO PARAGRAPH 26

Sandoz does not dispute that Medi-Cal used various discounts from AWP across time in certain instances to reimburse for Sandoz drugs, but denies any inference that discounted AWP was the only measure used. Medi-Cal reimbursed providers based on various formulas, including Federal Upper Limits, the state MAC and usual and customary. *See* CAL. CODE REGS. tit. 22, § 51513 (2002); CAL. WELF. & INST. CODE § 14105.45 (2004). Sandoz' expert calculated that Medi-Cal reimbursed only 14% of the claims at issue in this case for Sandoz drugs at the discounted AWP reimbursement benchmark. *See* Weedman Decl. Ex. R (Ex. 2a of Expert Report of Daniel L. Rubinfeld); *see also* Weedman Decl. Ex. S (Errata Sheet for Expert Report of Daniel L. Rubinfeld).

Dated: January 15, 2010

By: /s/ Wayne A. Cross

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CERTIFICATE OF SERVICE

I, Jacqueline L. Chung, hereby certify that on January 15, 2010, I have caused true and correct copies of the foregoing Defendant Sandoz Inc.'s Response to Plaintiffs' Local Rule 56.1 Statement of Undisputed Facts as to Sandoz Inc. to be served on all counsel of record by electronic service, pursuant to the Case Management Order No. 2 entered in by Honorable Patti B. Saris in MDL 1456.

/s/ Jacqueline L. Chung
Jacqueline L. Chung